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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,883

10/13/2005

Ryan S. Bardsley

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07/22/2008

DALY, CROWLEY, MOFFORD & DURKEE, LLP
SUITE 301A
354A TURNPIKE STREET
CANTON, MA 02021-2714

EXAMINER

FERNSTROM, KURT

ART UNIT

PAPER NUMBER

3711

NOTIFICATION DATE

DELIVERY MODE

07/22/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@dc-m.com
amk@dc-m.com

Office Action Summary	Application No. 10/552,883	Applicant(s) BARDSLEY ET AL.	
	Examiner Kurt Fernstrom	Art Unit 3711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
4a) Of the above claim(s) 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-12, 16-19, 21-35, 43 and 44 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 13-15, 20, 21 and 35-42 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-44 in the reply filed on April 25, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of these claims recites terminology which lacks antecedent basis – “the simulated skin” in claim 10; “the inner core” in claim 12 - due to apparent errors in listing the claim from which these claims are intended to depend. Applicant is advised to review all claims to ensure that dependency is as intended, as there are other claims which appear to depend from the “wrong” claims (e.g. claims 43 and 44).

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Nicholls. Nicholls discloses a simulated body part comprising a simulated skin covering, and simulated veins, which are considered to constitute a blood container, such that realistic sensory feedback is provided. With respect to claims 31-32, visual feedback in the form of simulated bleeding is disclosed by Nicholls. With respect to claim 33, the skin is elastic, and thus inherently deforms when a needle is inserted therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9, 11, 12, 16, 17, 19, 26-29, 34 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls. Nicholls discloses all of the limitations of claims 1-5 with the exception of the holding container. However, Official Notice is taken that holding containers are very well known, for shipping and storage purposes, and

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would be obvious to provide to the device of Nicholls. With respect to claim 11, Nicholls discloses an inner core. With respect to claim 12, while Nicholls does not explicitly disclose the recited characteristics of the core, such would have been obvious for providing a realistic simulation. With respect to claim 16, Nicholls discloses that the device simulates a human arm. With respect to claims 17, 19 and 43, bifurcated needles and surgical gloves are known in the surgical arts and would have been obvious to provide to the simulator of Nicholls. With respect to claims 26-29, the recited features of the holding container are well known, and would have been obvious to one of ordinary skill in the art. Also, instructions for using a kit, including those in CD form, are well known and obvious. With respect to claim 34, while Nicholls does not explicitly disclose the recited characteristics of the simulated skin covering, such would have been obvious for providing a realistic simulation.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls in view of Aboud. Nicholls discloses all of the claimed limitations with the exception of the recited viscosity of the blood. However, it is well known in the art of surgical simulators to provide simulated blood having a viscosity similar to that of real blood, as disclosed for example by Aboud. It would have been obvious to one of ordinary skill in the relevant art to modify the teachings of Nicholls by providing simulated blood having a viscosity similar to that of real blood for the purpose of enhancing the realism of the simulation.

Claims 18 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls in view of Lampotang. Nicholls discloses all of the claimed limitations with

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the exception of the syringe and associated needle as recited. However, this feature is known in the art, as disclosed for example by Lampotang. It would have been obvious to one of ordinary skill in the relevant art to modify the teachings of Nicholls by providing a syringe and associated needle for the purpose of instructing a user in the use of these items.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls in view of Kohnke. Nicholls discloses all of the claimed limitations with the exception of the stand as recited. Kohnke discloses a surgical simulator in the form of an arm, and further comprising a stand 13 in the shape of a shoulder having retention means 23 and 24 which supports the training device. It would have been obvious to one of ordinary skill in the relevant art to modify the teachings of Nicholls by providing a stand in the form of a shoulder for the purpose of supporting the arm-shaped simulated body part to facilitate use. Claim 24 recites language which is essentially functional, as the recited configuration depends on the heights of the table, chair and user. With respect to claim 25, magnets are very well known, and are considered to be an obvious variation on the teachings of Kohnke.

Allowable Subject Matter

Claims 7, 8, 13-15, 20, 21 and 35-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a device having all of the claimed limitations. In particular, with respect to claims 7, 36 and 37, there is no suggestion of a bag and sponge configuration as recited. With respect to claims 13 and 35, there is no suggestion of a blood container situated between a simulated skin and an inner core as recited. With respect to claim 20, there is no suggestion of a container having the recited features. With respect to claim 38, there is no suggestion of a pump and processor which have the recited features. As a result, these claims and their dependents contain allowable subject matter.

Applicant is advised that claim 10 is allowable only because it depends from claim 7. As discussed above, it appears that the dependency was not correctly listed. If claim 10 were to depend from claim 9, as appears to have been the intent, the claim would be rejected for reasons similar to those underlying the rejection of claim 9.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Szinicz, Cooper, Stoloff, Keegan, Fisher, Day, Haver, Wise and Baldwin disclose various surgical training devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kurt Fernstrom whose telephone number is (571) 272-4422. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Kim can be reached on 571 272-4463. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kurt Fernstrom/
Primary Examiner, Art Unit 3711

July 16, 2008